Version Number: 2	**Research & Development Policy 151-08**	Supersedes Document Dated: 11/20/2009
Effective Date: 03/15/2010	**Exempt Research**	Expiration Date: 03/14/2014

1 POLICY

It is Syracuse VA Medical Center IRB's policy to comply with all applicable federal, state, and local guidelines in the conduct of clinical research studies. Written procedures are required to guide the IRB and R&D Committee in the exempt review of research.

2 DEFINITIONS – Refer to Appendix C of Syracuse VAMC SOP 151-01

3 FORMS

Request for Exemption from IRB Review
Continuing Review form – Exempt Research
Amendment Form – Exempt Research

4 REFERENCES

45 CFR 46
38 CFR 16
VHA Handbook 1200.5 Requirements for the Protection of Human Subjects in Research

5 PROCEDURE

All research meeting the DHHS or FDA definition of human subject research must be reviewed by the IRB. For studies in which exemption is being requested, **the Institutional Review Board (IRB) chair, co-chair or designee (herein referred to as the IRB) must review and approve the exempt status,** not the investigator, other individuals or other entities. Following this determination of IRB exemption, the protocol is then reviewed by the Research and Development (R&D) Committee, R&D Chair, or designee (herein referred to as the R&D) and thereafter annually.

The application and accompanying documents (which includes the protocol, the Request to Review Research IRB Application, Conflict of Interest form, & Data Security Checklist for Principal Investigators) are submitted by the investigator to provide information that enables the IRB to determine if exemption meets the required criteria. The IRB review includes consideration of the following:

- Whether vulnerable subjects will be included
- If vulnerable subjects will be included, information concerning additional safeguards to protect the rights and welfare of these subjects
- Whether subject selection is equitable - which includes consideration of inclusion and exclusion criteria, recruitment methods, purpose of research, setting in which the research will be conducted
- Anticipated benefits and importance of knowledge
- Risks of the research

- Impact of study design on risk – with consideration of such things as the appropriateness of the design and whether the design will yield useful data
- Whether risks have been minimized:
  - by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk:
  - whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- Methods to obtain data
- Protecting confidentiality
- Whether informed consent and HIPAA regulations apply
- In addition, the IRB will consider whether the proposed project supports the VA mission and if there are any ethical or other issues.

38CFR16.101(b)

Research activities in which the only involvement of human subjects will be in one or more of the minimal risk categories listed below are exempt from the requirements of the Common Rule:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This exemption does not apply if the setting is not commonly recognized as an educational one, or if other than normal educational practices are employed. Even if the research is exempt, the investigator has an ethical obligation to ensure that students' rights and welfare are respected. When educational institutions become engaged in the actual conduct of research, they are required to file an Assurance in accordance with VA regulations at 38CFR16.103(a). This exemption does not apply if the research involves prisoners or is FDA-regulated.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation ***or (VHA 1200.5) place the subject at risk for loss of insurability****. This exemption does not apply if the research involves prisoners or is FDA-regulated. This exemption does not apply to research involving children when the research includes observation of public behavior where the investigator participates in the activities being observer, survey procedures, or interview procedures.*

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s)without exception that the confidentiality of the personally identifiable information will be maintained throughout the

research and thereafter. This exemption does not apply if the research involves prisoners or is FDA-regulated.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This exemption does not apply if the research involves prisoners or is FDA-regulated.

NOTE: The information must exist at the time the research is proposed and initiated.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv)possible changes in methods or levels of payment for benefits or services under those programs. Research in this category must: a) Be conducted pursuant to federal statutory authority, b) Have no statutory requirements for IRB review, c) Not involve significant physical invasions or intrusions upon the privacy interests of participants, AND d) Have authorization or concurrence by the funding agency. This exemption does not apply if the research involves prisoners or is FDA-regulated.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. This exemption does not apply if the research involves prisoners (See Determining Whether a Proposed Activity is Research Involving Human Subjects According to FDA or DHHS Regulatory Definitions).

Investigator Procedures

Investigators wishing to have a research protocol or protocol amendment exempted from IRB review must present the request in writing, along with the research proposal and required forms, to the IRB Office. The investigator must indicate the specific criterion, from those listed above {38CFR16.101 (b)(1-6)}, believed to be appropriate for exempting the proposal. The investigator is to follow the procedures applicable to the type of item submitted (i.e., if a new proposal, all required forms must be submitted). Once approved, it is the Investigator's responsibility to assure that the research project continues to meet the criteria for exemption from IRB review. Any unusual or untoward events must be reported as required by SOP 151-17. All exempt protocols will have continuing review at least annually by the Research and Development (R&D) Committee.

R&D Office Administrative Procedures

Upon receipt of a request for exemption, R&D Office staff will check for completeness and assign the review to the IRB chair, co-chair or an IRB member designated by the IRB chair or co-chair. The protocol and materials are entered into MIRB. For initial reviews, the IRB Chair/designee will complete the Request for Exempt Review, noting the category of the law that is met. For proposed changes in a project that has been previously approved as exempt, the IRB Chair/designee will document their decision for approval of the changes and whether the project continues to meet the criteria for exemption on the Annual Review by R&D Committee for IRB-Exempt Research form. Documentation of verified exemptions, inclusive of the basis for the exemption according to federal regulations, will be documented in the minutes of the R&D Committee. VA policy does not permit a research project to begin until the R&D Committee's review and approval is obtained.

Once approved, the Research Service staff will generate a letter of approval which will include the category of exemption and the R&D Committee Chair's, co-Chair's, or designee's signature and date. The ACOS/R&D will sign all approval letters. The R&D Committee approval date becomes the anniversary date for the purpose of continuing review to occur within 365 days. This letter is forwarded to the Principal Investigator. If it is determined that the project does not qualify for exemption, the principal investigator is also notified that a full IRB application will be required.

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